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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/286,166	04/05/99	FOWLKES D	CPI-012CP4BC

000959
LAHIVE & COCKFIELD
28 STATE STREET
BOSTON MA 02109

HM22/0824

EXAMINER	
BRANNOCK,M	
ART UNIT	**PAPER NUMBER**
1646	9

DATE MAILED: 08/24/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
09/286,166	Fowlkes, DM et al.
Examiner	**Group Art Unit**
Michael Brannock, Ph.D.	1646

☒ Responsive to communication(s) filed on *May 19, 2000*

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *3* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claim

☒ Claim(s) *43-51* is/are pending in the applicat

Of the above, claim(s) _____ is/are withdrawn from consideration

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *43-51* is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☒ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____ .

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). *8*

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

— SEE OFFICE ACTION ON THE FOLLOWING PAGES —

DETAILED ACTION

Status of Application: Claims and Amendments

1. This Office Action supersedes that of Paper 6, 2/17/00. The Office Action of Paper 6 is vacated. Thus, Applicant need not respond to the Office Action of Paper 6, but must respond only to the instant Office Action.

2. Applicant's preliminary amendments of Paper 7, entered 3/20/00 but originally received 12/08/99, have been entered in full.

3. Claims 43-51 are pending

Specification

4. The instant specification does not comply with 37 C.F.R. § 1.821(d) which requires a reference to a particular sequence identifier (SEQ ID NO:) be made in the specification and claims wherever a reference is made to that sequence. Correction is required. See M.P.E.P. 2422.04. Also, the instant application fails to comply with sequence rules because there is no paper copy of the Sequence listing, i.e., a paper copy cannot be transferred. The instant application must contain a paper copy of the sequence listing as supplied by Applicant through amendment.

Double Patenting

5. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible

harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

6. Claims 43-51 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-47 of U.S. Patent No. 6100042. Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 1-47 of U.S. Patent No. 610042 contain the elements of the instant claims 43-51 but claims 1-47 of U.S. Patent No. 610042 also require that a heterologous polypeptide be expressed by the cells and translocated to a location allowing the polypeptide to interact with the heterologous G-protein coupled receptor - this additional limitation is not required by the instant claims. Thus, the instant claims recite open claim language and embrace the patented subject matter. A species (e.g. the patented claims) renders obvious a genus (e.g. the pending claims).

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are

such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. Claims 43, 44, 45, 47, 50 and 51 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5284746 in view of Kang, YS. et al. Mol. Cell. Biol. 10(2582-2590)1990.

U.S. Patent No. 5284746 discloses a transformed yeast cell comprising a reporter gene (see col 12, L43, e.g. LacZ see col 12, L65-66) under the control of a pheromone-responsive promoter (see col 12, L42; e.g. FUS1 promoter see col 12, L48-56), a heterologous mammalian G-protein coupled receptor gene (β2- adrenergic receptor, for example, see col 1), wherein said receptor is a hybrid receptor comprising intracellular sequences from yeast and sequences from heterologous receptors (see col 3, L2), wherein said yeast receptor sequences are STE2 sequences (see col 4, L33), wherein said receptor is capable of inducing yeast pheromone response (see col 4, L5), each gene being under the control of a separate promoter (second construct) (see col 12, L 41), and a mutation in the ste2 gene causing increased sensitivity to receptor activation (see col 10, L8-9).

The disclosure of U.S. Patent No. 5284746 does not teach a hybrid Gα protein comprising yeast Gα nor an otherwise heterologous Gα protein. Kang, Y.S. et al. (supra) disclose heterologous yeast/mammalian hybrid Gα proteins expressed in yeast that complement the cell cycle arrest in cells lacking endogenous Gα (scg1 mutant cells) (see page 258, 3rd para).

Conversely, U.S. Patent No. 5284746 teaches that heterologous hybrid yeast\ mammalian G-protein-coupled-receptors can induce cell cycle arrest in cells lacking the endogenous receptor (see col 4, line 25-35). Therefore, it would be obvious to one of ordinary skill in the art at the time the invention was made, with reasonable expectation of success, to use hybrid Gα proteins instead of hybrid G-protein receptors in the assay disclosed in U.S. Patent No. 5284746. The motivation to do so was provided by Kang et al. (supra) who stated that portions of mammalian Gα proteins (Gαi) which bind to mammalian receptors but do not interact with yeast βγ subunits could be made to do so by expressing them as hybrid proteins containing yeast sequences (See table 2).

9. Claims 46, 47 and 49 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5284746 and Kang, YS. et al. Mol. Cell. Biol. 10(2582-2590)1990 for the reasons put forth above regarding claims 43, 44, 45, 47, 50 and 51, and in further view of Chang, F. and Herskowitz, I. (Cell 63 [999-1011]1990).

The disclosure of U.S. Patent No. 5284746 in view of Kang, YS. et al. includes the elements of claims 43, 44, 45, 47, 50 and 51 as discussed above, with the exception that neither reference teach a mutation in the FAR1 gene which permits transcriptional activation of pheromone-responsive genes without cell cycle arrest. Chang and Herskowitz (supra) teach that mutations in the FAR1 gene permit transcriptional activation of pheromone-responsive genes without cell cycle arrest (see the abstract and Figure 1). Therefore, it would have been obvious to

one of ordinary skill in the art at the time the invention was made, with reasonable expectation of success, to include mutations in the FAR1 gene (as disclosed by Chang and Herskowitz) when using the assay disclosed in U.S. Patent No. 5284746, modified as taught by Kang, YS. et al. The motivation to do so is provided by the teachings of Chang and Herskowitz (supra) who state that FAR1 mutations allow for the observation of pheromone-responsive transcription in dividing cells, i.e. in the absence of cell cycle arrest (see para 1, pg 1001 of Chang and Herskowitz) - pheromone-responsive transcription being required to drive reporter gene expression as taught U.S. Patent No. 5284746 (see col 12).

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Brannock, Ph.D., whose telephone number is (703) 306-5876. The examiner can normally be reached on Mondays through Fridays from 8:00 a.m. to 4:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, Ph.D., can be reached at (703) 308-6564.

Official papers filed by fax should be directed to (703) 308-4242. Faxed draft or informal communications with the examiner should be directed to (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Elizabeth C. Kemmerer

ELIZABETH KEMMERER
PRIMARY EXAMINER

John J. Doll, Director
Technology Center 1600

MB

August 8, 2000

Application No.: 09286166

NOTICE TO COMPLY WITH REQUIREMENTS FOR PATENT APPLICATIONS CONTAINING NUCLEOTIDE SEQUENCE AND/OR AMINO ACID SEQUENCE DISCLOSURES

The nucleotide and/or amino acid sequence disclosure contained in this application does not comply with the requirements for such a disclosure as set forth in 37 C.F.R. 1.821 - 1.825 for the following reason(s):

[X] 1. This application clearly fails to comply with the requirements of 37 C.F.R. 1.821-1.825. Applicant's attention is directed to these regulations, published at 1114 OG 29, May 15, 1990 and at 55 FR 18230, May 1, 1990.

[X] 2. This application does not contain, as a separate part of the disclosure on paper copy, a "Sequence Listing" as required by 37 C.F.R. 1.821(c).

[ ] 3. A copy of the "Sequence Listing" in computer readable form has not been submitted as required by 37 C.F.R. 1.821(e).

[ ] 4. A copy of the "Sequence Listing" in computer readable form has been submitted. However, the content of the computer readable form does not comply with the requirements of 37 C.F.R. 1.822 and/or 1.823, as indicated on the attached copy of the marked -up "Raw Sequence Listing."

[ ] 5. The computer readable form that has been filed with this application has been found to be damaged and/or unreadable as indicated on the attached CRF Diskette Problem Report. A Substitute computer readable form must be submitted as required by 37 C.F.R. 1.825(d).

[ ] 6. The paper copy of the "Sequence Listing" is not the same as the computer readable from of the "Sequence Listing" as required by 37 C.F.R. 1.821(e).

[ ] 7. Other: _____

Applicant Must Provide:

[ ] An initial or substitute computer readable form (CRF) copy of the "Sequence Listing".

[X] An initial or substitute paper copy of the "Sequence Listing", as well as an amendment directing its entry into the specification.

[X] A statement that the content of the paper and computer readable copies are the same and, where applicable, include no new matter, as required by 37 C.F.R. 1.821(e) or 1.821(f) or 1.821(g) or 1.825(b) or 1.825(d).

For questions regarding compliance to these requirements, please contact:

For Rules Interpretation, call (703) 308-4216
For CRF Submission Help, call (703) 308-4212
For PatentIn software help, call (703) 308-6856

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